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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/863,063	05/21/2001	David Greenstein	N-7088 DWS	7595

7590

10/02/2002

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EXAMINER

TELLER, ROY R

ART UNIT

PAPER NUMBER

1653

7

DATE MAILED: 10/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/863,063		GREENSTEIN ET AL.	
	Examiner		Art Unit	
	Roy Teller		1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 1-33 and 40-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6</u> . | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-18, drawn to a method of identifying an anti-nematode agent by contacting a test compound to a nematode, classified in class 800, subclass 3.
 - II. Claims 19-27 and 32, drawn to a method of using an anti-nematode agent, classified in class 424, subclass 9.1.
 - III. Claim 28, drawn to the process of making an anti-nematode agent, classified in various classes and subclasses.
 - IV. Claims 29-31, drawn to a method of identifying an anti-nematode agent by detecting compounds that bind major sperm protein, classified in class 530, subclass 350.
 - V. Claims 34-39, drawn to a nematode major sperm protein, classified in class 530, subclass 350.
 - VI. Claims 40,41, and 45, drawn to an antibody, classified in class 530, subclass 387.1.
 - VII. Claims 42-45, drawn to an antibody, classified in class 530, subclass 387.1.
- Claim 45, drawn to the production of an antibody is generic to inventions VI or VII and will be examined if the applicant elects invention VI or VII.

The inventions are distinct, each from the other because of the following reasons:

The methods of each inventions I-IV are materially different and plurally independent from each other because each is practiced with materially different process steps and require

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materially distinct protocols and reagents. The purpose of inventions I-III is different. The purpose of II-IV is different. The transgenic for I is not required for IV. The process used in IV is not required for group I. The methods of group I-III are distinct from invention V. Inventions I, II and III do not require the protein of invention V and the protein does not require the methods of invention I-III. The burden required to search inventions I-III and V together would be undue.

Inventions IV and V are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP 806.05(e)). In this case the method can be performed using the method of invention I and the protein can be used to isolate antibodies.

Inventions I-IV and VI or VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP 808.01). In the instant case the methods of inventions I-IV do not require the antibodies of inventions VI and VII and the antibodies do not require the methods of inventions I-IV. The burden required to search the methods with the antibody would be undue.

Inventions V and VI or VII are patentably distinct and separate from each other because the polypeptide of invention V Can be used to stimulate female sexual maturation while the antibody can be used to antagonize the protein. The protein structure and function of MSP and antibodies against MSP are materially distinct and separate. The burden required to search inventions V and VI or VII together would be undue.

Inventions VI and VII are patentably distinct because the purpose of group VI is to bind the sheath cell contraction domain of MSP while the purpose of invention VII is to bind the oocyte maturation domain. The structure and function are materially distinct and separate. The burden required to search inventions V and VI or VII together would be undue.

Because these inventions are distinct for reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination is indicated as proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

During a telephone conversation with Douglas Schelling on August 20, 2002 a provisional election was made without traverse to prosecute the invention of group V, claims 34-39. Affirmation of this election must be made by applicant in replying to this office action. Claims 1-33 and 40-45 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 34-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 34, line 4 “capable of” doesn’t describe or define whether stimulation of female sexual maturation actually occurred or if it is only possible. How big is the domain that is capable of stimulating? Is it 125 amino acid residues or is it 2 residues. Note that in claim 34, line 2 “or fewer consecutive amino acids” is indefinite also.

Claims 35-39 contain the same indefinite language as claim 34, i.e.- “capable of”.

Claims 35, 37, and 38 contain the same or similar indefinite language as claim 34, i.e.- “or fewer consecutive” or “or fewer”.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 34-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller (Science, vol. 291, pp. 2144-47, 2001) in view of the *C. elegans* sequencing consortium (Science, vol. 282, pp. 2012-18, 1998). Miller shows that major sperm protein (MSP) is a signal for oocyte maturation during *C. elegans* reproduction (see abstract). The *C. elegans* sequencing consortium teaches the sequence of *C. elegans* major sperm protein with 99.6% similarity to SEQ ID. NO: 2 of applicant's. It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine Miller and the *C. elegans* sequencing consortium data. Miller teaches that the exceptionally high degree of conservation in nematodes makes major sperm protein (MSP) an attractive anti-helminthic drug target (pg. 2147). The *C. elegans* sequencing consortium teaches that the sequence shows the long-range relationships between genes and provides the structural and control elements that must lie among them (pg. 2016).

Conclusion

Claims 34-39 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is (703) 305-4243. The examiner can normally be reached on Monday- Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (703) 308-2923. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

RT
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RT

Christopher S. F. Low
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SUPERVISORY PATENT EXAMINER
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